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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,122	11/12/2003	Jurgen Brinkhues	9003-286US	6214

570 7590 10/23/2006

AKIN GUMP STRAUSS HAUER & FELD L.L.P.  
ONE COMMERCE SQUARE  
2005 MARKET STREET, SUITE 2200  
PHILADELPHIA, PA 19103

EXAMINER

MEHTA, BHISMA

ART UNIT PAPER NUMBER

3767

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/706,122	BRINKHUES, JURGEN	
	<b>Examiner</b>	<b>Art Unit</b>	
	Bhisma Mehta	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 12 October 2006.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.  
4a) Of the above claim(s) 1-14 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 15-20 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 12 November 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/12/2003</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group III in the reply filed on October 12 2006 is acknowledged.
2. Claims 1-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 12 2006.

### ***Information Disclosure Statement***

3. Parts of the information disclosure statement filed November 12 2003 fail to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. A copy of the documents, which have been crossed out, was not provided and, therefore, these documents have not been considered.

### ***Drawings***

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 6b. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid

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abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

5. The abstract of the disclosure is objected to because it is too long. Correction is required. See MPEP § 608.01(b).

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over McConnaughey (U.S. Patent No. 2,895,773) in view of Pharma Gummi Wimmer West GmbH (EP 0 148 426) ("Pharma Gummi"). In Figure 3, McConnaughey shows a piston stopper comprising a one-piece rubber base body (307) with a receiving cavity (310) for connecting with a displacement transferring element (320) and a piston section (302a).

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The outer circumference of the piston element (302a) abuts against a syringe cylinder (320) as seen in Figure 3a. The piston stopper has an uncoated sealing section (303b) adjacent to the piston section (302a) and which abuts against the syringe cylinder (320). At least one continuous sealing tip (302b) and an annular continuous sealing zone (302c) are provided on the outer circumference of the sealing section (303b). At least a portion of the sealing zone (302c) is provided as a straight extension to an outer circumference of the piston section (302a) and abuts against a syringe cylinder (320) or slightly projects beyond a portion of the outer circumference of the piston section (302a). In Figure 3, McConnaughey show a section of an inside wall of the piston stopper with an internal thread (304b) to connect with a thread (322b) of the displacement transferring element (320) where the internal thread (304b) terminates at a spacing from a bottom (306) of the receiving cavity (310). The section with the internal thread (304b) terminates at the piston section (302a) or at a spacing from it and a cylindrical or tapered receiving cavity (at 321c in Figure 3a) extends between the internal thread (304b) and the section of the receiving cavity (310) which extends into the piston section (302a). As seen in Figure 3a, a cross-section of the receiving cavity (310) tapers out from the bottom (306) of the receiving cavity toward an opening of the receiving cavity. McConnaughey discloses the piston stopper substantially as claimed. However, McConnaughey is silent on the piston section being enclosed in a cap-shaped inert film where the film comprises a fluorinated polymer film. In Figure 18, Pharma Gummi show a rubber piston stopper (33) having multiple sealing lips (34, 35, 36) and, in lines 310 of page 29, Pharma Gummi teach enclosing a piston section (37) of the

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piston stopper in a cap-shaped inert film (8) comprising a fluorinated polymer film. It would have been obvious to one having ordinary skill in the art at the time the invention was made to enclose the piston section of McConnaughey in a cap-shaped inert film such as a fluorinated polymer film as taught by Pharma Gummi as Pharma Gummi teach that it is well known to provide an inert film on a piston section of a piston stopper which is facing the contents of a syringe cylinder to avoid unwanted interaction between the contents of the syringe cylinder and the rubber portion of the piston stopper (see line 16 of page 8 to line 10 of page 9).

### ***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Balisky (U.S. Patent No. 4,820,278), Godat et al (U.S. Patent No. 5,472,431), Grimard (U.S. Patent No. 5,489,266), and Yarborough et al (U.S. Patent No. 6,626,870) disclose piston stoppers with multiple sealing lips.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



BM

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

